CSFEU091

Site visit report for travel to Germany and Belgium to collect data for the supplemental Classical Swine Fever (CSF) risk assessment, June 20, 2000 - June 28, 2000

Executive Summary:

On June 22, 23, 26, and 27, a Veterinary Services (VS) team (Jerry Freier, CEAH; Ken Forsythe, CEAH; Anne Goodman, NCIE) conducted a site visit in Germany and Belgium to collect data for a supplemental analysis of the importation risk for Classical Swine Fever (CSF) from the European Union (EU). The need for a supplemental analysis was identified from comments made on APHIS's May 3, 1999, risk assessment and the associated proposed rule [Fed. Reg. 64(122), Friday, June 25, 1999, 34155] to import breeding swine, swine semen, and fresh and frozen pork from the EU

In response to comments from a peer review panel, the public (including the US pork industry), and the Office of Risk Assessment and Cost Benefit Analysis (ORACBA), VS agreed to perform a supplemental descriptive risk assessment focusing on spatial and temporal aspects of CSF movement from affected to unaffected areas within the EU. Approximately three weeks prior to departure, VS issued a formal request for data from the EU on the origin of outbreaks in space and time, any information available on disease surveillance in feral swine and wild boars, data on animal movement, maps of local veterinary administrative units in areas where outbreaks occurred (including information identifying and differentiating between outbreak locations inside and outside of quarantine of control zones), and information on herd and animal density in the EU. The data were intended for use in a descriptive analysis comparing pathways and extent of spread from primary sources in a Geographic Information System (GIS) format.

The site visit was scheduled as a follow-up to the request. The team was sent to collect the necessary supporting data for the assessment.

Member States (MSs) participating in the discussion were limited to those which had detected recent outbreaks of CSF in wild boar or domestic pigs. MSs providing information were Germany, Belgium, Luxembourg, Spain, Italy, France, and The Netherlands.

Because the information sought in this site visit was specific for a particular analysis, the report will address only information on those topics. Previous site visit reports address the EU's earlier responses to requests for information needed to conduct previous risk assessments concerning the issue (Report on Site Visit to European Member States Concerning Animal Disease Status, cover memo from John L. Williams, January 9, 1998, and Site Visit to the European Union, USDA/APHIS/VS, December 1, 1997).

Schedule of and logistics of visit:

The team was accompanied during the entire visit by Dr. Alberto Laddomada, Animal Health and Live Animals Legislation Unit, Directorate-General for Health and Consumer Protection, European Commission. The group visited with representatives of the Federal Research Centre for Virus Diseases of Animals in Wusterhausen, Germany on June 22 and 23. The Centre is

internationally recognized as a WHO collaborating center for rabies and is also responsible for epidemiological surveillance and control systems for CSF in Germany.

Germany was chosen by the European Union (EU) as a site to visit, at least in part, because of its history of CSF in wild boar. Presumably, Germany's recent problems have been more severe than those of some other member states. However, it is likely that the team was specifically invited to visit Germany also because the EU considers Germany's program to address CSF in wild boar to be a model effort.

The team observed that the data presented in Germany addressed specifically the information request which had preceded the visit, almost item by item.

The team traveled subsequently to Brussels for June 26 and 27 meetings with personnel from the European Commission and Member States (MS) in which CSF has been detected in wild boar or domestic pigs. Dr. Alex Thiermann accompanied the team during this stage of the visit. On the first day, the team listened to formal presentations from the EU Commission and Member States.

On the second day, the team met with Dr. Laddomada, who provided some of the documents requested. During this meeting the group generated two lists: one was of documents received and the other, of documents promised. As of July 20, all information requested by VS had been provided.

Information presented by Member States:

*1. **ANIMO***

The ANIMO system was described in a series of presentations from the EU Commission perspective and from the perspective of individual MSs. The series of presentations described the background, process, and configuration of ANIMO as well as current functioning of ANIMO in the Mss. Animal movement data for breeding swine and swine semen exports to other MSs were provided as printouts generated from the system.

ANIMO was created at the request of Member States to monitor animal movement. It was developed and is administered by a private contractor located in Dublin. It is not controlled directly by the Commission. Use of a private contractor may result from concern by Member States regarding issues of confidentiality.

Each MS is responsible for entry and report generation of its own data. MSs can only access information on shipments with which they have been sender or receiver. Although ANIMO practices and policies of individual MSs may differ, a common thread is that the local veterinary unit (LVU) in the smallest administrative district of the MS is responsible for entering data into the system and for quality control.

A. Commission Perspective on ANIMO

A speaker from the Commission described the legislative basis for various aspects of the system, including for the infrastructure, the network, the equipment configuration, the model message, identification codes, the role of LVUs in the system, the cooperation between ANIMO host centers and Member States, and linkages between administrative and technical aspects of the system. The ANIMO record or the "message" includes the origin and destination of the product or animals being shipped, health certification provisions, means of transport (including lorry identification number), details of the responsible LVU. The message is sent from point of origin to MS receiving consignments.

In addition to the ANIMO record which travels electronically, a health certificate accompanies the shipment. LVUs (presumably at both origin and destination) check for accuracy and take any control measures considered necessary.

Codes have been established for species, type of animal (production, slaughter), product in order to minimize language barriers (electronic files provided by EU). Animals and products from MSs and third countries may be traced. The system is easily updated. Data are stored on the host computer for 1 year.

Some member states have national servers. Member States with national server centers can identify restriction areas and stop movements easily on their own. Although the contractor in Dublin performs this service for Member States which do not have national servers, there was no indication that this appears to produce a significant delay in notification.

Costs are prorated by message and paid by the LVU. The system was touted as the best animal movement system in the world.

B. Belgian perspective on ANIMO

Belgium's ANIMO system differs from that of other MSs. Although the CSF situation in the country has proved the system to be useful, Belgium has initiated additional checks. One of these is its approach to health certification. In this, the consignee provides information to its LVU and consignor sends information to receiving LVU before a message is entered into ANIMO. Ear tags are given to farm of destination. Pigs come with a health certificate, a copy of which is sent to LVU. The ANIMO message is sent within 24 hours.

In addition, an epidemiological surveillance system is associated with the ANIMO system in Belgium. All pig farms are identified and visited by inspectors from the LVU three times per year. The inspector performs routine controls, looking at the number of animals, the number of pigs, and the identification system. A report is filed electronically and can be accessed for comparison and revision at the next inspection.

There is no central server in Belgium.

C. German perspective on ANIMO

German presenters described the role of the LVU in disease control and its interaction with both the Federal government and the EU Commission. Control measures are handled at the district level. Districts are responsible for informing neighboring districts in the event of an outbreak. Border inspections are conducted for imports from third countries. In Germany, the LVU, district and kreis constitute the same unit. The kreis level VMO is responsible for all field activities.

German applications of ANIMO system for tracking animal and product movement were also discussed. In addition to the ANIMO computer record, hard copy certificates are provided to document that animals or products have moved. Veterinarians at the point of departure and the point of arrival are responsible for the certification. LVUs are responsible for data entry. Germany is one of 5 EU countries which has a national server for ANIMO.

The system was demonstrated on-line in Germany. Realistic queries were generated, and rapid responses were received. Examples of consolidated data on the movement of animals and products from German kreis to MSs were retrieved and provided to the team. Although the system can report data for shipments to smaller administrative units, the Germans were unwilling to provide information at this level for reasons of confidentiality.

The Germans suggested that collection centers may influence ANIMO data. In this regard, animals may be sent to a collection center before being shipped elsewhere. The collection center may appear initially to be the final destination.

The German discussion also addressed spatial and temporal data used in a GIS-based disease reporting system in Germany and the use of GIS in animal disease control in Germany. This presentation included a description of Germany's computerized national disease control system, Tierseuchenbericht(?) (TSN), which was developed and is maintained in Wusterhausen. Data are entered at the district level when disease is observed. Input is menu-driven to facilitate uniformity and completeness. Data entered address the potential for spread or the distance-dependency. For example, potential for disease spread from animals located at a market is considered distance independent since the animals could be shipped to far distant locations. Local veterinary authorities also input census data and farm location. The system was demonstrated.

D. Spanish perspective on ANIMO

Spain's ANIMO system operates through a national server. There are 60 LVU and 22 border inspection units which track movement and identify problems.

Spain considers the system to be particularly useful for pigs since there is a lot of pig movement. Most pigs are imported to Spain for fattening and sent to other Member States for slaughter. In 1999, Spain received 3300 pig messages from other Member States. This represented import of 1.5 M pigs. Of these, approximately 1M were for fattening, the rest for slaughter. Fattening

pigs come primarily from The Netherlands, Germany, and France. With respect to animals leaving for slaughter, there were 5200 messages representing 1.25 M pigs. Most of these (0.9M) went to Portugal. The primary traffic pathway is from The Netherlands through Spain to Portugal.

Spain has its own information technology (IT) unit. The IT unit can tell whether the LVU has read a particular message. If not, the LVU can be reminded to do so.

The ANIMO message identifies the type of farm, health status, and identifies any problems justifying restricted movement. Spain would like ANIMO to be expanded to include disease control capacity.

E. French perspective on ANIMO

France's ANIMO system has a national server. Border units constitute part of the network to monitor for CSF.

France's pig breeding regions represented by twelve departments (zones), 3 of which constitute 70% of production. One zone sends pigs to Germany and breeding animals to Spain; one deals primarily with Belgian imports and exports; one sends animals to southern Spain. Between December 1999 and May 2000, most shipments came from Germany and the Netherlands to Eastern France (Rhone Valley)

F. Italian perspective on ANIMO

Italy's ANIMO system is similar to that of other countries. It has no central server. There are 250 LVU and 2500 VMOs.

Italy received approximately 7500 consignments with 1.4 M head from other Member States in 1999. Animals come primarily from the Netherlands (piglets); some come from Germany and Denmark, and slaughter pigs come from Spain.

Animals must be registered. Importers use a standard form and can check messages on a daily basis.

If a risk is perceived, Italy sends messages to other MSs which received the risky consignment. Italy has a double notification similar to that described for Belgium (certification at local level prior to entry into ANIMO). Italy has no national server, so it must notify other Member States through Dublin, whereas Belgium can notify directly.

G. Luxembourg perspective on ANIMO

Luxembourg's ANIMO system is very small. The LVU in Luxembourg is equivalent to the national level.

H. The Netherlands perspective on ANIMO

The Netherlands ANIMO system has a national server. Data on export are available immediately. The Netherlands has a unique farm number which is used for tracing disease. The country has a local system of notification within 24 hours before arrival in addition to ANIMO.

I. Quality Control of ANIMO

Quality control of the ANIMO system relies primarily with the LVU which is responsible for data input and should have a sense of what is happening as a result of its daily responsibilities, and therefore, is primarily under Member State control. The LVU can compare the ANIMO record with health certificate, inspect arrival and departure premises, and perform random checks.

However, in addition to the LVU, the Commission's Food and Veterinary Office (FVO) in Dublin conducts inspections (The Commission's Replies to the Court of Auditors Special Report No. 1/2000 on Classical Swine Fever, Official Journal of the European Communities, C 85/1, March 23,2000). As of July, 2000, the FVO hac performed two inspections on certification and functioning of ANIMO in Member States in the year 2000 (e-mail from Alberto Laddomada to K. Forsythe and A. Theirmann, 6/27/00). The reports of these inspections were being finalized at the time the e-mail was sent. Three additional inspections were planned for the second half of the year. In addition, the EC has stated that the ANIMO system will be subject to more checks on its functioning and the implementation of relevant legislation by the Member States (Commission reply, p. 24)

The Court of Auditors provides an additional level of oversight. Its 1999 report was fairly critical of ANIMO. However, Dr. Laddomada stated that the Court of Auditors report was misleading because it identified lack of entry of certain information as a problem, when that information was well-known by the LVU. He characterized the missing information primarily as multiple analogous shipments between the same premises. The premises were not always entered because the information was repetitive and known to the LVU.

In addition to the overall EC perspective on quality control of ANIMO, individual member states commented on the issue.

Belgium relies on correspondence with computer records and health certificates, spot checks. However, local information doesn't correspond 100%. There is no statistical tool. Although the total number of movements is considered reliable, the number of animals may not always be. Entry in Belgium is more efficient than it has been in the past.

The Netherlands can inform Member States within minutes after a suspect case is identified.

In Italy, the LVU notifies the central office when a lack of correspondence is observed.

In Germany, faxes are sent in place of computer messages if the system breaks down.

France checks that holding in country of destination exists. It conducts an investigation if there is no correspondence. It also performs random checks on arriving animals.

In Spain, the local veterinarian performs an administrative check to determine if the designated farm is allowed to receive animals and may conduct inspections. The frequency of checks is dependent on the origin of the animals, in that checks are more frequent if there is reason for suspicion. The local veterinary service maintains contact with the central service which passes information to Member States. Correspondence between information in the system and on the message is assessed.

2. Classical swine fever in domestic and feral pigs in 1999-2000

Surveillance and control systems in individual states were described. Demographic data for Belgium, France, Germany, Italy, and The Netherlands were provided as electronic files on disks.

A. CSF in France

France has been monitoring wild boar since 1991 (Information on classical swine fever situation in the feral pigs in Bas-Rhine and Moselle, France, 1999). Its plan (CSF epidemiosurveillance in French wild boars, 1998) includes increased monitoring in Moselle and Bas-Rhine zones near the German border. These regions have had outbreaks in wild boar. However, the wild boar population is separate from domestic pigs. Wild boar in found in the east and are contained in a well-described and surveyed zone. Domestic pigs are in the western part of the country. Southwestern France sells pigs to Spain; Northwestern France to Belgium and Germany.

Epidemiological data show a marked drop-off in the number of cases observed viologically and serologically since 1993. The country has not detected disease by virus isolation in wild boars since 1997 in the infected zone and since 1995 in the surveillance zone, although serologicaly positive animals were detected in both zones through 1998 (1999 publication). Seropositive animals were not young animals, possibly suggesting they did not reflect new infections. Surveillance is ongoing in both affected and surveillance zones. Animal movement is restricted in the affected area, and eradication measures remain in place. France has had no outbreak in domestic pigs that appeared to have originated from wild boar for 12 years, despite the presence of infected wild boar (meeting notes).

B. CSF in Luxembourg

Luxembourg's last outbreak was in 1987. However, Luxembourg established a surveillance zone because disease was detected in a neighboring state in Germany in October, 1999. During the increased surveillance period, 5 wild boar were serologicaly positive out of 80 boar tested, but no virologicaly positive wild boar were identified in Luxembourg. One of the positive animals was a house pig, but the diagnosis of that animal was not confirmed when re-tested at a laboratory in Belgium.

Movement restrictions are in place for domestic pigs in the surveillance zone. Specifically, pigs can't move until they are tested by both serology and virology. Pigs in the surveillance zone are identified by ear tags. There are 85K domestic pigs in the surveillance area, which covers 11 cities and covers 300 km2. The country has an area of 2500 km2.

The contingency plan for boar in the surveillance area includes increased surveillance and attempts to reduce the numbers of boar less than 1 year old. No trade of live animals is permitted. The approach is very similar to that taken in Germany.

All boar killed must be tested and collected in special containers. No virus positive boar have been detected out of 293 tested, although seropositive animals have been detected. Surveillance does not suggest that the disease is spreading in wild boar.

Other details of the contingency plan are provided in the Luxembourg report. Luxembourg is taking a relatively conservative approach in that it has a contingency plan in place despite the fact that one is not required by EU legislation, since the EU does not consider that Luxembourg is affected. Because of this, the plan has not been approved by the Standing Veterinary Committee. However, it is similar to the German plan for the adjacent area, which apparently has been approved.

Dr. Laddomada suggested that epidemiological data indicate a tendency for disease to spread east.

C. CSF in Belgium

Belgium has detected no virologicaly positive wild boar since 1997, and it has been screening since 1993. However, serologically positive animals were detected in 1998. Approximately 100 boar are tested per province in three provinces where wild boar are concentrated. The total wild boar population in those provinces was estimated at 13K. The situation is identical with Luxembourg.

A surveillance zone was defined around a virologically positive animal detected in 1999. The animal was identified 1 km from the eastern border close to the Rhineland-Pfalz region in Germany which is a restricted area because of disease in wild boar. Larger numbers of samples were taken in the surveillance zone. Restriction measures were similar to those in Luxembourg.. No treatment is allowed for ill pigs. Local disease control centers collect information on disease and movement into and out of the zone.

In 1999/2000, 361 boar were sampled (blood for serology, kidneys and tonsil for virology); 931 tests were performed. One/361 gave an atypical reaction, and another one was seropositive. Financial awards are given for cooperation. No spread is apparent to domestic pigs.

D. CSF in Italy

Italy implemented an eradication plan in 1997 in its affected northern province (Lombardi/Varese) in conformance with EU legislation (80/217/EEC). Security was enhanced for domestic pigs, even though there aren't many in the area. Ultimately, the pigs were slaughtered. Apparently disease didn't spread in subsequent years.

Surveillance data suggest that both serologically positive and virus positive animals have decreased, although virus-positive wild boar were discovered in the 1998/99 hunting season. Italy tested 664 animals in 1998/99 of which more than 50% were seropositive and 91 animals were virus positive. The virus type was the same as that detected in Varese, but it wasn't clear that was the origin (meeting notes).

In 2000, Italy tested 751 wild boar in the Varese Province, 41% of which were seropositive and only 3 were virus positive.

CSF is endemic in wild boar in Sardinia, primarily in the eastern and western zones. There appear to be approximately 250K boar on the island, although this number is associated with a high level of uncertainty. Domestic pig movement restricted. No virus has escaped from Sardinia in 10 years (meeting notes), although 649 wild boar were tested in 2000 and 365 were serologically positive.

The number of outbreaks reported is decreasing (CSF in Italy graph presented to USDA 6/26/00) Three outbreaks occurred in domestic pigs in 1999, one primary in Vercelli Province, in the northern part of the country and two secondary outbreaks, one in Vercelli and one in Parma Province, also generally north but not adjacent to Vercelli.

E. Germany

Various levels of government operate to control CSF in Germany, including federal, laender, and kreis (Public Veterinary Service in the Federal Republic of Germany, FMFAF, 1999). The most important of these in the control of CSF is the kreis or district level, since the federal government has no direct control over kreis activities. There are 438 districts (kreis) in Germany.

Germany presented epidemiological data on CSF outbreaks, including information on the origin of the outbreak as well as spread of disease during various outbreaks from an historical perspective. The presentation described what appear to be changing trends (i.e., reduction in number of outbreaks and spread to secondary, tertiary outbreaks) with time.

Detailed reports on six CSF outbreaks which occurred in Germany in 1999 were reviewed (Detailed Reports on Classical Swine Fever, Germany, 1999). The reports include information on the location of the outbreak, the distance from the nearest holding, the type and size of farm, the date and identifying individual for suspect cases, the clinical findings (serology and/or virology) diagnosis, the laboratory making the diagnosis, the date of confirmation, depopulation information (date, method of depopulation), identification of the number of blood samples taken

at the time of depopulation, the test methodology used for those samples (serology, virology), trace back to source of outbreak, trace forward to farms which received animals, and whether any of the premises involved (forward or back) were located in protection or surveillance zones.

All six outbreaks appeared to originate from wild boar, as the serotype diagnosed was identical as that in wild boar in the areas. All of them occurred within previously established protection or surveillance zones. Therefore, movement of domestic pigs from these areas will be restricted by the measures described in Community legislation (Council Directive 80/217/EEC).

One of the six outbreaks documented was confirmed 6 days after confirmation in an adjacent farm (5 meters away). Surveillance at the second farm was conducted because of suspect cases on the first farm. The Germans used adjacency in space and time and as justification for classifying these two occurrences of disease as a single primary outbreak, rather than a primary and secondary (Classical Swine Fever situation in Germany, May 5, 2000, report to the Standing Veterinary Commission presented May 10, 2000), even though the occurrences were documented separately in individual detailed reports. Definition of the protection and surveillance zones and approach to surveillance and control measures for these outbreaks are addressed generally in various sources (Classical Swine Fever in Wild Boar, Aug. 10, 1999; Edwards, et al., Vet. Microbiol., 2000; Laddomada, Vet Microbiol., 2000; Council Directive 80/217/EEC; Classical Swine Fever (CSF) situation in Germany, May 5, 2000, report to the Standing Veterinary Commission on May 10, 2000).

Data were presented on the number of CSF outbreaks in Germany since 1980 (FMFAF, 1999) in a line graph depicting the number of outbreaks by year. Spread of disease appeared as peaks in the graph. Generally, the trend in the total number of outbreaks was a reduction in the number (1015 in 1984; 118 in 1990; 100 in 1993; 117 in 1995 and no more than 52 (in 1996) since 1995.

The data were processed through the TSN system developed in the institute. This data base is used to collect and process epidemiological information and provide information to OIE, other European Member States, third countries, and for use in official publications. The questionnaire providing information for entry into the data base is extensive and was described as 20 pages long.

Germany contained 12 M pigs in 1935. 23-26 M is the current count. In 1990, the count was to 31M. This is number is larger than it had been in the past because it reflected the population after reunification. Currently 10% are breeding pigs.

The number of farms is decreasing. There were 1M in 1970; approximately 300K in the early 1990s; and 150K now.

The Germans provided a significant amount of detail on the feral swine/wild boar situation. German policies in this area are based on epidemiological data.

To reduce risk of spread, disease must be detected ASAP. Previously, it was German policy to kill all animals (including adults) in an area 500 meters beyond the outbreak. That policy has

now changed because epidemiological data suggest that disease can spread slowly and may be harder to detect in low density pig populations. Current policy is to kill young animals, which are more likely to be infected. Adult animals acting strangely and found dead are a focus of hunting and testing. Epidemiological characteristics of wild boar upon which German policies (as well as those of other member states) are described in "Classical Swine Fever in Wild Boar," Scientific Committee on Animal Health and Animal Welfare, Adopted August 10, 1999.

Germany considers that it has lost vaccination as a tool. The current EU policy does not allow vaccination since it is impossible to distinguish between vaccinated and infected pigs. However, there is some interest in developing a marker vaccine that can make that distinction and the EU is sponsoring research on the issue (Short report on the results of the large-scale laboratory trial on the Classical Swine Fever Marker Vaccines, VA/7627/99).

The Germans commented that there were generally not a lot of wild boar in areas where there are a lot of domestic pigs.

Details of the surveillance and control activities in wild boar in Germany and the data which have been obtained were provided (CSF situation in Germany, May 5, 2000). Surveillance and control activities depend heavily on hunter cooperation in providing samples. The German government has produced a public relations video to educate hunters in order to improve the quality of samples obtained. The team watched the video, which explains to hunters that wild boar killed in a restricted area should be collected in special blue bags. Restricted areas are posted. All dead animals should be collected and submitted for testing. Hunters are encouraged to kill sub-adults and piglets, rather than adult pigs. Areas in which outbreaks were identified in 1999 were Brandenberg, Mecklinburg-Vorpommern, Neidersachen, Baden Wuttemberg, Reinland-Pfalz (problems shared with France, Belgium, Luxembourg), and Saxony Anhalt. Data from 2000 were presented also.

The general approach to dealing with outbreaks, both domestic pigs and wild boar, is defined in Community Legislation (80/217/EEC). However, specific control mechanisms for wild boar and domestic pigs are defined by the Member States in contingency plans which they develop to address individual situations and submit for approval to the Standing Veterinary Committee, once an outbreak in wild boar is suspected. Germany has six plans for 1999, one for each area in which an outbreak was detected. The plan is developed at the local level by a group composed of veterinarians, biologists, and hunters. Boundaries of the restricted zone and surveillance zone are defined. Surveillance (serological and virological tests) is increased within the zones. However, in addition, screening (at a level of 30% in Germany) is ongoing in uninfected areas.

Within restricted areas, domestic pigs must be kept isolated from contact with wild animals. Veterinary inspection of farms occurs monthly. Inspector looks at fences, takes blood samples for testing, looks for clinical signs. Trade out of the area is restricted; live pigs can not be taken to other MS. Farms can only sell animals to other parts of Germany, and then only with proper certification, testing and holding periods. As a result of these policies, Germany observed a decrease in CSF in domestic pigs.

Level of surveillance is categorized by number of samples - zero, less than 29, and more than 58. The last number represents sampling at different levels, depending on the level of the restriction in the area.

Wild boar are monitored outside the restricted area. In 1999, 27,500 samples were tested serologically and 10,700 were tested for virus. This represents approximately 15% of the wild boar population hunted. Surveillance samples are limited to hunting and road kill samples. Limitations of this approach were mentioned, including deteriorated condition of some samples.

Surveillance in domestic pigs is conducted to detect 10% prevalence with 95% confidence. One positive serology is considered sufficient to focus energies in the area but not to declare the area affected.

In Germany, outbreaks in wild boar are not always coincident with outbreaks in domestic pigs. However, in the ones which have been associated, recent outbreaks in domestic pigs have been detected and held to primary outbreaks.

3. Lessons learned from and actions taken as a result of the 1997-1998 epidemic

A portion of the discussion was devoted to the lessons learned by both the Commission and individual Member States during the 1997-1998 epidemic. This focused in part on disease prevention measures but also development of specific policies to identify and control outbreaks as well as generation of guidelines for implementation of those policies.

A. EC perspective on lessons learned

At the Commission level, these actions include proposed changes in EU legislation; emphasis on creation of contingency plans by Member States; changes in attitude toward and monitoring practices for semen, which wasn't previously considered a high risk commodity (summary presented in Commission reply to Court of Auditor's report, p.25); and issuance of guidelines on various aspects of CSF diagnosis and control in a diagnostic manual under preparation.

Since the outbreak, the EC has placed more emphasis on the timely establishment of contingency plans within MSs than it did previously. This emphasis is in accordance with the recommendations in the Court of Auditor's report. Relevant to this, the Standing Veterinary Committee has reviewed all plans submitted in the last 2 years. New plans have been approved. Inspections of local situations have occurred in 7 states. Other inspections are planned and ongoing. When the inspection reports are finalized, they are posted on the Internet.

The Court of Auditors criticized Commission management for not being sufficiently active in taking into account experiences and changes in scientific knowledge. The Court felt that progress had been slow in developing a specific strategy to tackle outbreaks of disease. The Commission does not agree with that position. It feels that Member States should be respected, that LVUs know their individual situations best; and that they should be intimately involved in

surveillance and control activities. Rather, the Commissions feels that its role is to evaluate and advise.

The Commission is revising 80/217/EEC. The team was informed that there is not a lot that is entirely new. Rather, there is more detailed guidance for control in high density areas, dealing with wild boar, swill feeding (additional controls in plants heat-treating swill and farms using swill).

The issue of high density areas and their use to set policies was discussed. The definition provided by Dr. Laddomada differed from that used by the German government. The EC definition included a value 300 pigs/km2, along with some additional criteria. Rationale for the definition is presented in a document provided to the team (Definition of DPLAs and SPLAs, Annex I, no date) and based on epidemiological data. The definitions were described as risk factors used to establish disease control measures. Other measures taken into consideration were neighborhood factors (Hans Laevens, Ph.D. Thesis, 1999).

Specific measures for consideration include eradication, control, and vaccination. Criteria have been established for preventive killing. These criteria are intended to address situations like the cessation of preventive killing in the Netherlands that may have contributed to the rapid spread of disease in 1997 (EC response to the Court of Auditor's report).

Vaccination is still under consideration, even though it is prohibited by current EU policy. The reason for this is that no diagnostic test is available which can distinguish a marker vaccine from a field infection. The EU will continue its non-vaccination policy for the present but will provide guidelines for use of a marker vaccine in case a good diagnostic test is developed.

Control measures are being defined in a diagnostic manual. These are being generated as guidelines. They explain how to approach, establish and set boundaries for infected, surveillance, and buffer zones. For example, it is recommended that an infected zone be 3-10 km radius surrounding the outbreak (80/217/EEC). The 10 km value is considered preferable because data suggest that, if an outbreak is detected which is characterized as secondary, the primary outbreak probably occurred within the 10 km distance.

There were no new specific provisions for handling feral pigs. However, the team was informed that the guidelines for control of problems associated with them will be more detailed. Recommendations for restriction on movement of domestic pigs will be revised. MSs will have to adhere to the 90 day limit to present their eradication plan to the Standing Veterinary Committee.

Included in suggested actions regarding feral pigs will be to stop hunting in order to allow immunity to develop, let infected animals die naturally in order to decrease the level of susceptibles in the population, and initiate vaccination programs if experimental vaccines are available which can be differentiated from field infections. Dr. Laddomada hoped the legislation presenting guidelines would be published by 2001.

The definition of infected areas will be flexible and essentially unchanged from 1997. It will be defined at the local (LVU) level under Commission rules defined in Council Directive 80/217/EEC. This directive also recommends movement restrictions for domestic pigs.

Dr. Thiermann asked Dr. Laddomada if the US would receive notification of suspicion at the same time as MSs. There was some equivocation in the response to that question. It appeared that the EU didn't want to notify the US of "suspicion," in case the outbreak was not confirmed. Dr. Laddomada indicated that, if the outbreak were a secondary one, even the EU might not be informed immediately because notification isn't required for secondary outbreaks. However, he said that, under the equivalency agreement, the US and EU agree to share information, notification.

B. Belgian perspective on lessons learned

The Belgian representative stressed the need to act quickly if an outbreak occurs. The representative wanted to be able to use marker vaccines. He stressed the importance of defining control measures "in peacetime," i.e., prior to development of a problem. A desire to protect high density areas was expressed. Although preventive slaughter was described as critical, particularly in high density areas, the Belgian representative also expressed a desire to keep surveillance zones small to control costs. A need for close cooperation with the pig sector was recommended. Finally, Belgium also stressed the need continue testing animals slaughtered even after disease has been confirmed.

C. German perspective on lessons learned

Germany listed several lessons learned. These included the need to (1) establish effective kreis units to coordinate disease control; (2) create expert groups at the local level to trace back/forward; (3) develop a standardized and complete (20 page) questionnaire to collect data; (4) immediately block contact farms over a 6 week period; (5) establish rules for risk assessment relative to contacts, density of pigs and farms; (6) work with police to implement policies at local level (politicians supported this in Germany); (7) cull and safely dispose of pigs; (8) continue sampling after confirmation of disease, during culling, and in neighborhood; (9) use appropriate definition of pig density; (10) focus on diagnosis as critical; (11) consider public relations important; (12) commit to efficient computer-based animal system; (13) hold training exercises (Germany has a course/year); (14) always suspect CSF for sick animals whether you think the disease is that or not; (15) keep emergency plans updated; (16) use vaccine, even one which can be differentiated from field strain, only in emergency; (17) write policy changes into legislation (surveillance by police has been so included in Germany); (18) bring new experiences into emergency plan and legislation ASAP.

C. Spanish perspective on lessons learned

Disease was absent from Spain for 12 years before its reappearance in 1997. The country was regionalized at the comarcas level. Domestic pigs could only be shipped to other comarcas for slaughter. Pig density is high in Lerida Province, where the outbreak occurred, but not so high in

other affected comarcas. It was more difficult to eradicate disease in comarcas with high pig density, so disease persisted longer. However, a national plan which defined measures to be taken with regard to suspect cases, movement controls, training, reorganization of the pig sector, and surveillance, allowed Spain to demonstrate that disease was eradicated (meeting notes and OIE posting on Internet). Sampling was conducted at several levels, including (1) 100% of farms were tested for serology in affected areas, (2) 50% of farms were tested in adjacent areas, (3) lower levels were tested in surrounding areas, and (4) the rest of the nation. Each farm was tested twice.

The sampling data obtained provided background data which were written into operational manuals for local veterinarians. Issues covered in the manual included guidance on locations to test, level of sampling, disinfection procedures for vehicles and lorries, and the role of police. The manual will also describe measures to take in case of disease suspicion with respect to surrounding farms and preventive killing. Because of the risk in high density areas, legislation is being enacted that prohibits formation of new high density areas. Marker vaccines will be used only in the context of an international agreement.

The result of these activities was that Spain declared itself free of CSF, with EU concurrence, in January, 1999 (http://www.oie.int/info/AIS_33.HTM#Sec1).

D. French perspective on lessons learned

France has had no CSF disease in domestic swine for 12 years, although it does have disease in feral swine in Moselle and Bas Rhine, which are adjacent to the Rhineland-Pfalz region in Germany. The Rhineland-Pfalz region contains a wild boar restricted area.

E. Italian perspective on lessons learned

Italy has instituted contingency plans for field veterinarians, training courses. It recognizes the need for good cooperation between diverse groups. It recommends monitoring animals found dead, increased surveillance and monitoring in suspect areas.

F. The Netherlands perspective on lessons learned

The pig population is The Netherlands is quite dense, particularly in the southern and eastern part of the country. There are 2.5 to 3.0K pigs/km2. The country produces 24M piglets/yr. Turnover of breeding material is high. There is a high level of specialization. Transport levels are also high.

Aspects of the 1997 outbreak were described. It was diagnosed on Feb. 4, 1997 in a breeding farm with 1800 pigs. Health problems had been observed for several weeks. The disease origin was proposed to be infected wild boar in Germany. Disease spread was exacerbated by cold weather and poorly cleaned and disinfected vehicles. Interruption of preemptive slaughter during the outbreak was also a factor. The outbreak has been described as the biggest and most costly

one so far within the EU (Diukhuizen, Prev. Vet Med.42, 135, 1999). More than 10 M pigs were slaughtered. Disease was not eradicated until May 1998.

The Netherlands considers public relations important. It promotes public education on risks of introduction and spreading of the through newspapers, professional and trade journals. It stresses the importance of quick detection of disease. It maintains contact with the pig industry, attempting to increase disease awareness and stressing importance of hygienic measures.

As part of its disease control activities, it has instituted a national alarm number; it conducts central and local exercises, and it monitors and updates its manual and contingency plan. It implemented new legislation this year to facilitate identification and tracing of animals, increase effectiveness of sanitary procedures, and more effectively control pig movements. It intends to monitor all pig farms, once a month or every two weeks. The regulations regarding pig movements are more restrictive than those promulgated by the EU. In this regard, the number of collection centers has been reduced, and new rules have been established for cleaning and disinfection of lorries.

Two semen centers were affected in the outbreak. It is not entirely clear how the first semen center became infected, although disease may have been transmitted from a lorry which had previously carried pigs to a slaughterhouse. Function of new lorries is now dedicated. The second semen center may have been infected by a boar received from the first semen center. Because it was in a protection zone with the first semen center, exchanges were allowed for a period of time. Apparently, such an exchange would no longer occur. Also, at the second center, semen from different boars was mixed before distribution to sow herds. This practice has ceased. Alternative sources of infection may have been contaminated boar semen, human contact or neighborhood infection (meeting notes and Elbers, et al., Prev. Vet Med. 42, 157, 1999).

In addition, new rules have been instituted for handling semen, transporting live animals, behavior of lorry drivers entering the artificial insemination (AI) center. An operational manual describes these procedures (meeting notes).

At the time of the outbreak, semen was not considered a high risk factor. That attitude has changed (Court of Auditors, 1999; Pluimers, et al., Prev. Vet. Med. 42:139, 1999)

The Netherlands detected a seropositive wild boar in 1999 (meeting notes, apparently not mentioned in a written report).

Domestic pig demographics haven't changed from the information provided previously.

4. Recommendations and actions

As of July 20, despite distrust by the EU of our political process and the need to conduct an additional analysis, all requested data were received. Almost immediately upon return of the site visit team, CEAH personnel began to enter the data into a comprehensive database designed to evaluate spatial-temporal aspects of recent outbreaks relative to CSF importation risks. Once the

data have undergone a preliminary evaluation an outline of the proposed approach will be presented for information and evaluation to VS management, members of the review team for the document, and ORACBA.

Based on the information which has been provided, specific issues which the assessment might address, either by GIS analysis or in general discussion include the following:

1. Presence in wild boar doesn't mean domestic animals will be infected. France is good example, because, although disease occurs in wild boar, none has been detected in domestic pigs for 12 years. This results from the fact that wild boar and domestic pigs are separate. Wild boar are in east and contained in well-described and surveyed zone. Domestic pigs in west..

2. Geographic separation between wild boar and domestic pig populations should reduce the risk of transmission from wild boar in some Member States, other than France, where the separation fairly clear.

3. Surveillance is carried out in both boar and domestic pigs in most Member States which have had outbreaks in the past 5 years. Contingency plans and surveillance activities for domestic/wild animals are integrated in countries with infected wild boar.

4. Change in trend of spread in Germany, is from primary-secondary-tertiary in earlier outbreaks to no spread beyond primary in 1999, suggesting extent of spread has been reduced. Are similar trends occurring in other MSs? Are other time-dependent changes evident? Preliminary evaluation of the data suggest that there are large increases in the numbers of secondary outbreaks from the outbreak in The Netherlands. Risk from these outbreaks may be more significant than those from wild boar.

5. Restrictions on movement of animals, product in areas where outbreak was observed may help control spread of outbreaks. What was the distribution of new outbreaks between areas already under restriction and those not under restriction?

6. Changes made (lessons learned) since 1997 could be discussed as enhanced awareness and tighter policies. Hopefully, this could correlate with spatial measurements

7. ANIMO and quality control will probably have to be discussed because of the Court of Auditors report.

8. Movement patterns of products, animals may demonstrate a relationship to movement of disease.

Anne Goodman
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Appendix A.

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